

REMARKS

Claims 1-18 are pending and stand rejected. All pending claims are believed to be allowable over the references cited by the Examiner as discussed below. Accordingly, a Notice of Allowance for the present application is respectfully requested.

Rejection Under 35 U.S.C. §102(b)

Claims 1, 3-11, 13-15, 17, and 18 stand rejected under 35 U.S.C. §102(b) as being anticipated by Liberman.

Independent claim 1 generally recites a method for removing a sentinel lymph node, including *injecting a radiological contrast agent* detectable by an imaging modality, identifying a sentinel lymph node by imaging *utilizing the imaging modality*, introducing a percutaneous excision device, and excising the identified sentinel lymph node, where the introducing and/or the excising is performed under guidance by imaging.

Independent claim 11 generally recites a method including injecting a radiological contrast agent and a second agent into an area of interest, imaging at least one area of draining lymph nodes utilizing a first imaging modality capable of detecting the radiological contrast agent, and excising, using a percutaneous excision device, the identified sentinel lymph node, where the imaging and/or excising includes detection of the sentinel lymph node utilizing the second agent to confirm identification of the sentinel lymph node.

In contrast, Liberman fails to disclose or suggest injecting a radiological contrast agent into the human breast and also fails to disclose or suggest identifying a sentinel lymph node using an imaging modality, as generally recited in the independent claims.

Specifically, Liberman discloses the use of a radioisotope and/or a blue contrast agent. (See, e.g., page 2, lines 3-5 of the second paragraph in Introduction and page 3, lines 1-2 of the second full paragraph). Neither the radioisotope nor the blue contrast agent is a radiological contrast agent. In particular, the radioisotope is not a radiological contrast agent and cannot be imaged by ultrasound, computerized tomography (CT) or magnetic resonance imaging (MRI). Instead, the radioisotope is detected by a “handheld C-Trak gamma probe” which does not create any images. (See, e.g., page 4, lines 1-7). The gamma counter merely quantifies radioactivity with audible clicks and/or with a number displayed on a screen. Although the gamma counter can help the user determine the approximate location of the sentinel lymph node (SLN), the

gamma counter is not an imaging device nor can it be used to guide a percutaneous procedure. For example, it does not provide any information on anatomy, the angle in which to position a device, how deep to penetrate with the device, etc. Moreover, lymphoscintigraphy is a nuclear medicine procedure, not radiological imaging. Lymphoscintigraphy can be used to identify the "hottest" spot in the axilla created by the accumulation of the radioisotope in the SLN and is a guide to the general location of the SLN.

In addition, the blue contrast agent is only directly seen by eye. (See, e.g., page 4, lines 4-7). The blue contrast agent thus is not visualized by any imaging modality.

Withdrawal of the rejection of independent claims 1 and 11 as well as claims 3-10, 13-15, 17, and 18 dependent therefrom under 35 U.S.C. §102(b) is respectfully requested.

Rejections Under 35 U.S.C. §103

Claims 2, 12, and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Liberman in view of Siczek.

However, dependent claims 2, 12, and 16 are believed to be allowable at least because the independent claims 1 and 11 from which they variously depend are allowable as discussed above.

In addition, Siczek does not overcome the deficiencies of Liberman as discussed above. In particular, Siczek describes using an MRI device to guide a medical instrument in the breast. The SLN is not in the breast but is typically in the adjacent axilla. In the diagrams, the various embodiments actually cover over the axilla, thereby making the axilla inaccessible to procedures.

Withdrawal of the rejection of claims 2, 12, and 16 under 35 U.S.C. §103(a) is respectfully requested.

CONCLUSION

Applicants believe that all pending claims are allowable and respectfully request a Notice of Allowance for this application from the Examiner. Should the Examiner believe that a telephone conference would expedite the prosecution of this application, the undersigned can be reached at the telephone number set out below.

In the unlikely event that the transmittal letter accompanying this document is separated from this document and the Patent Office determines that an Extension of Time under 37 CFR

1.136 and/or any other relief is required, Applicant hereby petitions for any required relief including Extensions of Time and/or any other relief and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **50-1217** (Order No. **MNOAP004**).

Respectfully submitted,



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